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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/421,213	10/20/1999	TIMOTHY J. O'BRIEN	D6064CIP	3804
27851	7590	07/27/2004	EXAMINER	
BENJAMIN A. ADLER 8011 CANDLE LANE HOUSTON, TX 77071			HARRIS, ALANA M	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/421,213

Applicant(s)

O'BRIEN ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) 22 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Arguments and Amendments***

1. Claims 22-24 are pending.  
  
Claim 22 has been amended.  
  
Claims 1-21, 23 and 25-52 have been cancelled.  
  
Claims 22 and 24 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Rejections***

#### ***Claim Rejections - 35 USC § 112***

3. The rejection of claim 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the cancellation of the claim.

#### ***Claim Rejections - 35 USC § 103***

4. The rejection of claims 22 and 24 under 35 U.S.C. 103(a) as being unpatentable over Japanese document, J09149790-A (10 June 1997) is withdrawn in light of the amendment to claim 22. Claim 23 has been cancelled.

***Specification***

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 55, line 16. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

***Maintained and New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 22 is vague and indefinite in the recitation "detectable labels for detecting said antibody." It is not clear if the antibody is labeled, a secondary antibody that detects the first antibody is labeled, there is free label in the kit or the protein is labeled. Applicants are requested to clarify. For purposes of examination the Examiner is interpreting the claim to read on a labeled antibody.

***Claim Rejections - 35 USC § 102***

8. The rejection of claim 24 under 35 U.S.C. 102(b) as being anticipated by Japanese document, J09149790-A (10 June 1997) is maintained.

Applicants assert that “[i]f one were to design an antibody based on the teachings of **J09149790-A**, the antibody would bind both the proteins and not bind specifically to TADG-15 protein.”, see page 5, first full paragraph of Remarks submitted May 7, 2004. Applicants conclude arguments with the assertion that “one skilled in the art are would never be able to anticipate an antibody that is specific to the domains other than the serine protease domain in order to bind specifically to TADG-15 protein.”, see bridging paragraph of pages 5 and 6 of the Remarks. These arguments and points of view have been carefully considered but found unpersuasive.

The anticipatory antibody disclosed in the Japanese document would specifically bind Applicants' TADG-15 protein (SEQ ID NO: 2). The Examiner is not clear on the two proteins noted in Applicants' response. Nonetheless, Applicants' claims do not include limitations that set forth a particular domain of SEQ ID NO: 2 should be bound or not bound by the claimed antibody. The claims do not include limitations that preclude the prior art's antibody from binding the TADG-15 protein and accordingly for the reasons set forth and of record the rejection is maintained.

***Claim Rejections - 35 USC § 103***

9. Claims 22 and 24 under 35 U.S.C. 103(a) as being unpatentable over Japanese document, J09149790-A (10 June 1997), in view of Harlow and Lane (Antibodies, A Laboratory Manual, pages 319, 321-325 and 340-352, 1988).

Applicants have amended claim 22 to include detectable labels to detect the bound antibody. Applicants outline the teachings of the specification and "...respectfully disagree with the Examiner's contention that the serine protease section of the TADG-15 protein would be ideal in generation of antibody contained in the detection kit", see Remarks, pages 7 and 8. These points of view have been carefully considered, but found unpersuasive.

The 102(b) maintained rejection set forth above plainly and clearly teaches an antibody that is specific for TADG-15 protein, SEQ ID NO: 2. Japanese document, J09149790-A does not teach a means to detect said antibody, or a kit for detecting TADG-15 comprising the antibody specific for TADG-15 and detectable labels for detecting said antibody.

Accordingly, although the claims recite a kit, no positive recitation of the kit ingredients/elements distinguishes the claim over the references. Therefore, the reference reads on the claimed kit. Further, it is a well-known convention in the art to place the recited elements in a kit for the advantages of convenience and economy, and methods of detection, diagnostics and therapies also were well known and available to the ordinarily skilled artisan. Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

Moreover, Harlow and Lane teach that monoclonal antibodies can be easily labeled. The reference teaches labeling of antibodies to be used in a wide range of immunological techniques. The antibodies can be labeled with an enzyme, biotin, fluorochromes and iodine as listed on page 322. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the teachings of Harlow and Lane. This basic antibodies manual provides protocols standardly used in immunology techniques. One of ordinary skill in the art would have been motivated to implement the teachings of both, the patent and Harlow and Lane in order to create labeled antibodies and antibody-conjugates in order to use them in a number of applications such as quantitative assays, pharmacokinetic assays, as well as for the discovery of new approaches to cancer therapy.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner can normally be reached on 6:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.  
19 July 2004